

REMARKS

Entry of this amendment and reconsideration of the subject application in view thereof are respectfully requested.

I. Claim Status

Claims 1-22 are pending in the application. These claims have been rejected and/or objected to. Claims 1, 3, 7-10, 12-16, 18-20 and 22 have been revised to clarify the invention. Claims 2, 4-6, 11, 17 and 21 have been canceled. New claims 23-26 have been presented. Applicant respectfully submits that no new matter is added by claim amendments.

II. Claim Rejections Under 35 U.S.C § 112, First Paragraph, Enablement

Claims 1-22 stood rejected under 35 U.S.C. § 112, first paragraph, as failing to satisfy enablement requirement.

In rejecting these claims, the Examiner makes various assertions on pages 2-5 of the Office Action. In particular, the Examiner contends that the specification, while being enabling for a crystalline Form VI atorvastatin calcium, does not reasonably provide enablement for hydrates of the crystalline form.

Without conceding the validity of the Examiner's assertions and solely to expedite the prosecution of this application, Applicant has elected to strike the appropriate claim language as suggested by the Examiner. In view of Applicant's election to present the invention in different terms, it is believed that the alleged grounds for this rejection have been rendered moot.

Reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, are respectfully requested.

III. Rejections Under 35 U.S.C. § 103

Claims 5 and 6 have been rejected under 35 U.S.C. § 103(a) as being obvious over WO 97/03958 ("Mackenzie"). This rejection is respectfully traversed and believed to be overcome in view of the following discussion:

Claims 5 and 6 depend from claim 1. Claim 5, in addition to the specific X-ray

diffraction pattern features recited in claim 1, further limits the independent claim by requiring that the crystalline Form VI atorvastatin calcium contain "up to 8 moles of water per mole of atorvastatin calcium." Likewise, claim 6 further limits the independent claim by requiring that the crystalline Form VI atorvastatin calcium contain "up to 8 moles of water per mole of atorvastatin calcium."

Mckenzie teaches a crystalline Form III atorvastatin. Mckenzie does not teach or suggest a crystalline Form VI atorvastatin calcium or hydrates thereof as set forth in claim 1.

The *Graham v. John Deere Co. of Kansas City*, 86 S. Ct. 684 (1966) factors control an obviousness inquiry. Those factors are: 1) "the scope and content of the prior art"; 2) the "differences between the prior art and the claims"; 3) "the level of ordinary skill in the pertinent art"; and 4) objective evidence of nonobviousness. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, at 1734 (2007) (quoting *Graham*, 383 U.S. at 17-18).

The Examiner admits that Mckenzie does not disclose the claimed crystalline Form VI with the specific X-ray powder diffraction pattern.

The Examiner attempts to establish *prima facie* obviousness and provides the rationale and motivation as set forth at page 7, first full paragraph, of the Office Action. It states that:

"Applicants have not shown any data (i.e., x-ray diffraction pattern) for the possible hydrates that are claimed in the invention . . . Also, Applicants have not shown in the specification the reason that Applicants have prepared hydrates of crystalline form VI and the benefits when compared to the crystalline form VI and hydrates known in the art."

First, the crystalline form VI and hydrates are not known in the art and the specification provides reasons that Applicants have prepared hydrates of crystalline form VI. *See, e.g.*, page 5, lines 21-30. Further, the Examiner has not cited any reference showing that the crystalline form VI and hydrates are known in the art. McKenzie (discussed above) is the only reference cited by the Examiner. Furthermore, the Examiner has not explained why Mckenzie teaching a crystalline Form III atorvastatin, useful as a hypolipidemic and hypocholesterolemic agent, could have promoted one of ordinary skill in the art to modify the prior art in a predictable manner to arrive at the claimed invention.

In order to establish a *prima facie* case of unpatentability in chemical cases, a showing

that the "prior art would have suggested making the specific modifications necessary to achieve the claimed invention" is also required. *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995). While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness analysis, the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination. *KSR*, 127 S. Ct. at 1731. Further, the Court indicated that there is "no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis." *Id.* As long as the test is not applied as a "rigid and mandatory" formula, that test can provide "helpful insight" to an obviousness inquiry. *Id.* Thus, in chemical cases, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound.

Applicant respectfully points out that the rejection on obviousness grounds cannot be sustained by mere conclusory statements (made on page 7 of the Office Action). Instead, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F. 3d 977 (Fed. Cir. 2006). The Examiner has not provided a sufficient reason or explicit analysis of why the McKenzie reference should be modified so as to arrive at the claimed invention.

If anything, there is evidence to the contrary. Specifically, the teachings of McKenzie contains no enabling methodology for preparing hydrates of crystalline Form III, let alone the crystalline form VI and hydrates. There is no suggestion in McKenzie that the proposed modification would be successful. Furthermore, "[p]redicting the formation of hydrates of a compound and the number of molecules of water incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of . . . [hydrates] and hence generalizations cannot be made for a series of related compounds." See the statements at page 4 of the Office Action. Therefore, the Examiner's rejection is believed to stand in error.

In view of the foregoing, Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness, of claims 5 and 6 or other pending claims, under

35 U.S.C. § 103(a). Even if *prima facie* obviousness has been established, which it has not, it is urged that the cited art nonetheless fails to render the present invention obvious under a proper § 103 analysis, as the proper suggestions and motivations are lacking in the cited reference. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

IV. Claim Rejections Under 35 U.S.C § 112, Second Paragraph

Claims 1 and 8-22 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims were rejected as indefiniteness for leaving a space after the term “15%” in claim 1 and for reciting in claims 8 and 9 the phrases “as shown in fig. 1” (claim 8) and “having formula of Fig. 1” (claim 9).

The rejection under 35 U.S.C. § 112, second paragraph, is rendered moot in view of the revised claims presented herein. Reconsideration and removal of the rejection are respectfully requested.

V. Claim Objections

The Examiner has objected to various claims as set forth at pages 8 and 9 of the Office Action.

Claim 2 was objected to as being of improper dependent form.

Claims 10-17 and 20-22 were objected to as being in an improper form because “a multiple dependent claim shall contain a reference, in the alternative only, to more than one claim previously set forth . . . and shall not serve as a basis for any other multiple dependent claim.”

“Claims 1, 3 and 7 are missing a period at the end of the claims. Claim 20 consists of two sentences . . . Claims 1 and 3 have the phrase ‘having characterized’ but should read ‘characterized’.”

Applicant respectfully believes that these objection has been overcome in view of the revised claims presented herein. Reconsideration is respectfully requested.

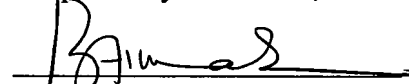
VI. Conclusion

Applicant believes this response to be a full and complete response to the Office Action. Accordingly, favorable reconsideration in view of this response and allowance of all of the pending claims are earnestly solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

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Respectfully submitted,



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